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Improvements in survival and clinical benefit with gemcitabine as first-line therapy for patients with advanced pancreas cancer: a randomized trial.

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PURPOSE: Most patients with advanced pancreas cancer experience pain and must limit their daily activities because of tumor-related symptoms. To date, no treatment has had a significant impact on the disease. In early studies with gemcitabine, patients with pancreas cancer experienced an improvement in disease-related symptoms. Based on those findings, a definitive trial was performed to assess the effectiveness of gemcitabine in patients with newly diagnosed advanced pancreas cancer. PATIENTS AND METHODS: One hundred twenty-six patients with advanced symptomatic pancreas cancer completed a lead-in period to characterize and stabilize pain and were randomized to receive either gemcitabine 1,000 mg/m2 weekly x 7 followed by 1 week of rest, then weekly x 3 every 4 weeks thereafter (63 patients), or to fluorouracil (5-FU) 600 mg/m2 once weekly (63 patients). The primary efficacy measure was clinical benefit response, which was a composite of measurements of pain (analgesic consumption and pain intensity), Karnofsky performance status, and weight. Clinical benefit required a sustained (> or = 4 weeks) improvement in at least one parameter without worsening in any others. Other measures of efficacy included response rate, time to progressive disease, and survival. RESULTS: Clinical benefit response was experienced by 23.8% of gemcitabine-treated patients compared with 4.8% of 5-FU-treated patients (P = .0022). The median survival durations were 5.65 and 4.41 months for gemcitabine-treated and 5-FU-treated patients, respectively (P = .0025). The survival rate at 12 months was 18% for gemcitabine patients and 2% for 5-FU patients. Treatment was well tolerated. CONCLUSION: This study demonstrates that gemcitabine is more effective than 5-FU in alleviation of some disease-related symptoms in patients with advanced, symptomatic pancreas cancer. Gemcitabine also confers a modest survival advantage over treatment with 5-FU.

Publication Types:

- Clinical trial
- Multicenter study
- Randomized controlled trial